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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/791,279	03/03/2004	Theodor Stern	26041	8931

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THE NATH LAW GROUP
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EXAMINER	
VAKILI, ZOHREH	
ART UNIT	PAPER NUMBER
1614	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/791,279	STERN ET AL.	
	Examiner	Art Unit	
	ZOHREH VAKILI	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 June 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-28* is/are pending in the application.

4a) Of the above claim(s) *27 and 28* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-28 are presented for examination.

A request for continued examination under 37 C.F.R. 1.114, including the fee set forth in 37 C.F.R. 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 C.F.R. 1.114, and the fee set forth in 37 C.F.R. 1.17(e) has been timely paid, the finality of the previous Office Action has been withdrawn pursuant to 37 C.F.R. 1.114. Applicant's submission filed June 2, 2009 has been received and entered into the present application.

Claims 1-26 are pending and are herein examined on the merits. Newly added claims 27 and 28 are withdrawn from consideration. Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 28 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a

foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-7, and 9-26 are rejected under 35 U.S.C. 102(b) as being anticipated by Fuisz (US Pat. No. 5518730).

Fuisz discloses a composition useful for a new controlled release delivery system using melt spun biodegradable polymers as a carrier or host material for a bio-effecting agent such as a pharmaceutical active or a hormonal compound (see col. 1, lines 5-10). Specific polymers useful in this composition include those marketed under the Medisorb and Biodel trademarks. The Medisorb materials are marketed by the Dupont Company of Wilmington, Del. and are generically identified as a "lactide/glycolide co-polymer". Four such polymers include: A) lactide/glycolide 100 L, believed to be 100% lactide; B) lactide/glycolide 100 PGA, believed to be **100% glycolide;** C) lactide/glycolide 85/15, believed to be 85% lactide and 15% glycolide; and D) lactide/glycolide 50/50, believed to be a copolymer of **50% lactide and 50% glycolide** (see col. 7, lines 5-17).

The bio-affecting active may be selected from any suitable drug, with a selected polymer the following therapeutic categories: uterine relaxants; vaginal preparations; and wound healing agents (col. 7, lines 62-64). Non-limiting examples of specific bio-effecting agents which may be useful in the present invention such as citric acid (see col. 8, line 20). The inventive compositions have great versatility in their application. The compositions can be used in steri-strip wound closure materials such as dressings and the like (see col. 9, lines 25-26). Further examples of additives which include polyalkylene oxides, such as polyethylene glycols, polypropylene glycols,

polyethylene-propylene glycols; and **glycerol** (col. 10, lines 60-63).

Consequently, the reference anticipates the claimed invention defined in claims 1-4 and 9-26.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

US Pub. No. 20070149731 A1 has a CIP Application No. 10074272 filed February 14, 2002 that predates the filing date of the instant Application. Application 10074272 discloses the same information as disclosed in US Pub. No. 20070149731 A1.

Claims 1-26 are rejected under 35 U.S.C. 102(e) as being anticipated by Myers (US PGPub. No. 20070149731).

Myers discloses a pH modulated films and methods of their preparation. The film compositions include at least one component having a non-neutral pH when combined with water (see abstract). Specific polymers useful include those marketed under the Medisorb and Biodel trademarks. The Medisorb materials are marketed by the Dupont Company of Wilmington, Del. and are generically identified as a "lactide/glycolide co-polymer". Four such polymers include: A) lactide/glycolide 100 L, believed to be 100% lactide; B) lactide/glycolide 100 L, believed to be **100% glycolide;** C) lactide/glycolide 85/15, believed to be 85% lactide and 15% glycolide; and D) lactide/glycolide 50/50, believed to be a copolymer of **50% lactide and 50% glycolide** (see paragraph 0102). The film compositions of the present invention may be applied to delivery substrates, such as **tampons or bandages**. For example, in one embodiment, a tampon is provided with two films where the first film includes a drug, and the second film is a pH modulated film including a buffer system. The second film permits the drug to cross vaginal membranes at a preferred pH (see paragraph 0122). Further examples of additives are polyalkylene oxides, such as polyethylene glycols, polypropylene glycols, polyethylene-propylene glycols, **glycerol**, glycerol monoacetate, diacetate or triacetate, triacetin, polysorbate, cetyl alcohol, propylene glycol, sorbitol, triethyl citrate, tributyl citrate, and the like, added in concentrations ranging from about 0.5% to about 30%, and desirably ranging from about 0.5% to about 20% based on the weight of the polymer (see paragraph 0157). The present example is directed to the incorporation of citric acid, and the film further included Tween 80 (see paragraph 0227, example 3).

Consequently, the reference anticipates the claimed invention defined in claims 1-26.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kluger et al. (US Pub. No. 2002/0045873 A1) and in view of Myers (US PGPub. No. 20070149731).

Kluger et al. teach a formulation effective in reducing the pH in a menstruating vagina or in a tampon inserted therein to below pH 5.5, comprising (a) 3-80% by weight of a solid organic acid polymer; (b) 92-15% by weight of a solid organic acid, and (c) 5-30% of a wetting agent. Also disclosed is a delivery system for releasing an active agent comprising: (a) a deposition comprising the active agent; and (b) a polymeric support on which the deposition is deposited, The delivery system is especially useful in a catamenial tampon for insertion in a human vagina which comprises (a) an inner core comprising an absorbent material; (b) an outer layer comprising a liquid permeable material; and (c) the delivery system (see abstract).

1. A formulation effective in reducing the pH in a menstruating vagina or in a tampon inserted therein to below pH 5.5 comprising: (a) 3-80% by weight of a solid organic acid polymer; (b) 92-15% by weight of a solid organic acid; and (c) 5-30% of a wetting agent.

2. A formulation according to claim 1 wherein said organic acid polymer is selected from the group consisting of polylactic acid, polyglycolic acid and polymalic acid.

3. A formulation according to claim 2 wherein said organic acid polymer is a lactide.

4. A formulation according to claim 3 wherein said organic acid polymer is DL-lactide or L-lactide.

5. A formulation according to claim 1 wherein said solid organic acid is selected from the group consisting of citric, malic, maleic, fumaric, succinic, tartaric and oxalic acids.

6. A formulation according to claim 1 wherein said wetting agent is selected from the group consisting of glycerol, polyethylene glycol (PEG), polypropylene glycol (PPG) and surfactants with an HLB ranging from 10 to 18.

7. A delivery system for releasing an active agent comprising: (a) a deposition comprising said active agent; and (b) a polymeric support on which said deposition is deposited.

8. A delivery system according to claim 7 wherein said active agent is a pH-reducing formulation.

9. A delivery system according to claim 8 wherein said pH-reducing formulation comprises: (a) 3-80% by weight of a solid organic acid polymer; (b) 92-15% by weight of an organic acid; and (c) optionally 5-30% of a wetting agent.

10. A delivery system according to claim 7 wherein the components of said deposition are dissolved in a solvent and the deposition is deposited by evaporation of said solvent.

11. A delivery system according to claim 7 wherein said polymeric support comprises a non woven polymer.

12. A delivery system according to claim 7 wherein said polymeric support is in the form of a strip.

13. A delivery system according to claim 12 wherein said strip consists of a plurality of layers.

14. A delivery system according to claim 13 wherein said strip consists of 2-16 layers.

15. A catamenial tampon for insertion in a human vagina comprising: (a) an inner core comprising an absorbent material; (b) an outer layer comprising a liquid permeable material; and (c) a delivery system according to any of claims 7-14.

16. A tampon according to claim 15 wherein said delivery system is positioned between said inner core and said outer layer.

17. A tampon according to claim 15 wherein said delivery system comprises a plurality of strips of the polymeric support.

18. A tampon according to claim 17 comprising 3 strips.

19. A tampon according to any of the previous claims wherein said delivery system incorporates a formulation effective in reducing the pH in the vagina of a menstruating woman or in a tampon inserted therein comprising: (a) 3-80% by weight of a solid organic acid polymer; (b) 92-15% by weight of an organic acid; and (c) optionally 5-30% of a wetting agent.

20. A tampon according to claim 19 wherein said organic acid polymer is

selected from the group consisting of polylactic acid, polyglycolic acid and polymalic acid.

21. A tampon according to claim 20 wherein said organic acid polymer is a lactide.

22. A tampon according to claim 21 wherein said organic acid polymer is DL-lactide or L-lactide.

23. A tampon according to claim 19 wherein said solid organic acid is selected from the group consisting of citric, malic, maleic, fumaric, succinic, tartaric and oxalic acids.

24. A tampon according to claim 19 wherein said wetting agent is selected from the group consisting of glycerol, polyethylene glycol (PCG), polypropylene glycol (PPG) and surfactants with an HLB ranging from 10 to 18.
(see claims 1-24).

Myers discloses a pH modulated films and methods of their preparation. The film compositions include at least one component having a non-neutral pH when combined with water (see abstract). Specific polymers useful include those marketed under the Medisorb and Biodel trademarks. The Medisorb materials are marketed by the Dupont Company of Wilmington, Del. and are generically identified as a "lactide/glycolide co-polymer". Four such polymers include: A) lactide/glycolide 100 L, believed to be 100% lactide; B) lactide/glycolide 100 L, believed to be **100% glycolide;** C) lactide/glycolide 85/15, believed to be 85% lactide and 15% glycolide; and D) lactide/glycolide 50/50, believed to be a copolymer of **50% lactide and 50% glycolide** (see paragraph 0102). The film compositions of the present invention may be applied to delivery substrates, such as **tampons or bandages**. For example, in one embodiment, a tampon is provided with two films where the first film includes a drug, and the second film is a pH modulated film including a buffer system. The second film permits the drug to cross

vaginal membranes at a preferred pH (see paragraph 0122). Further examples of additives are polyalkylene oxides, such as polyethylene glycols, polypropylene glycols, polyethylene-propylene glycols, **glycerol**, glycerol monoacetate, diacetate or triacetate, triacetin, polysorbate, cetyl alcohol, propylene glycol, sorbitol, triethyl citrate, tributyl citrate, and the like, added in concentrations ranging from about 0.5% to about 30%, and desirably ranging from about 0.5% to about 20% based on the weight of the polymer (see paragraph 0157). The present example is directed to the incorporation of citric acid, and the film further included Tween 80 (see paragraph 0227, example 3).

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed invention was made, to modify Kluger et al. formulation by further replacing lactide by glycolide. Myers discloses that lactide can be replaced by glycolide and vice versa.

A person of ordinary skill in the art would have been motivated to modify Kluger's formulation by further replacing glycolide as a solid organic acid polymer because it is prima facie obvious to combine two compositions each of which is taught in the prior art to be useful for same purpose in order to form third composition that is to be used for very the same purpose; idea of combining them flows logically from their having been individually taught in the prior art; thus, the claimed invention which is a combination of two known solid organic acid polymers set forth prima facie obvious subject matter. See In re-Kerkhoven, 205 USPQ 1069.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zohreh Vakili whose telephone number is 571-272-3099. The examiner can normally be reached on 8:30-5:00 Mon.-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Zohreh Vakili

Patent Examiner
1614

June 19, 2009

/Ardin Marschel/

Supervisory Patent Examiner, Art Unit 1614